Nelson, Bettie L

From: Nelson, Bettie L
Sent: Wednesday, November 13, 2002 10:18 AM
To: McCann, Amy Arnold
Cc: Osborne, Kevin (PMMC Legal)
Subject: DRAFT EMAIL TO MDS REGARDING PREGNANT SUBJECT

Amy,

Below is an email that I have composed to send to MDS to be used as part of their response to the subject in the long-term Accord JLI study who became pregnant during the course of the study.

Megan,

The Informed Consent which the subject was required to sign clearly states that pregnant women cannot participate in this study. The complete language is:

> **Cigarette smoking during pregnancy is associated with increased risk of spontaneous abortion, low birth weight infants, and perinatal mortality. Therefore, pregnant women cannot participate in this study and women of childbearing potential must avoid becoming pregnant during the study. Nicotine passes freely into breast milk and a nursing child may receive nicotine from a smoking mother's milk with the possibility of causing harmful side effects to the child. Therefore, women who are nursing cannot participate in this study. If you become pregnant during the study, you will be referred to a smoking cessation clinic.**

One of the exclusion criteria in the protocol (4.3) also indicates that "female subjects must not be pregnant or lactating or intend to become pregnant from screening through completion of the study".

Please make certain that the subject receives information regarding smoking and pregnancy and a referral to a smoking cessation program in your area.

If additional information is needed, please let me know.

With best regards,
Bettie

(804) 274-1502
(804) 334-5923 (Cellular)
(804) 274-3982 (Fax)

Tracking:	Recipient	Read
	McCann, Amy Arnold	Read: 11/13/2002 10:32 AM
	Osborne, Kevin (PMMC Legal)	

PM3006379723

Source: https://www.industrydocuments.ucsf.edu/docs/zkkj0001